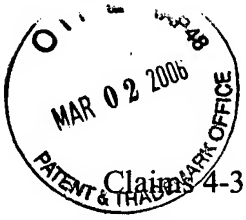

REMARKS

Claims 4-30 were pending in this application. Claims 4, 5, 8, 12-19, 22, 26-30 are canceled. Rejections of such claims are hereafter treated as moot. Applicants expressly reserve the right to pursue protection of any or all of the canceled subject matter in a continuing application. Claims 6, 7, 9-11, 20, 21, and 23-25 have been amended and new claims 31-36 have been added. No new matter is introduced by these amendments.

After entry of this amendment **claims 6, 7, 9-11, 20, 21, 23-25, and 31-36 are pending in this application**.

Examiner Interview:

Applicants thank Examiners Yao and Canella for the courtesy of an in-person examiner interview with their representative, Tanya M. Harding, on December 8, 2005. Also present at the interview was Cynthia Kanik as an observer on behalf of a licensee of the technology described in the application. During the interview, the priority date for and the written description rejection of the pending claims were discussed. Also discussed was the Amendment and Response to Non-Final Office Action, dated September 19, 2005 (the "September 19th Response"), which was submitted to the Office in connection with the sibling U.S. Patent Application No.10/648,631, filed August 25, 2003 ('631 Application). The '631 Application is directed to Pin1 polypeptides (including functional fragments thereof) and the present application is directed to Pin1 polynucleotides (including fragments thereof that encode functional fragments of a Pin1 polypeptide). Applicants' representative and the Examiners agreed that, given the parallel subject matter and the similarity of rejections issued in the two cases, claims in the present case likely would be allowable to the extent such claims recited polynucleotides encoding allowable polypeptides in the '631 Application. Applicants thank the Examiners for their helpful guidance and believe this Amendment conforms to discussions had during the interview.

Applicants have received the Examiner's interview summary, dated December 21, 2005. Applicants thank Examiner Yao for providing the summary, but note for the record that the interview was in person at the Patent Office rather than telephonic.

Specification Objections

The specification has been objected to for "lacking cross-reference information to parent applications." A priority claim reciting the lineage of the present application was added in "Amendments" filed on August 25, 2003. For thoroughness, this Amendment adds a header to the priority claim (*i.e.*, "Reference to Related Applications") and amends the form of the priority claim. In view of the foregoing information and amendment, Applicants request that this objection be withdrawn.

Priority

The present application claims priority through a number of related continuing and divisional applications (including U.S. Patent Application No. 09/275, 900; the '900 Application) to U.S. Patent Application No. 08/555,912, filed November 13, 1995 (the '912 Application). Notwithstanding the priority claim, the Office contends that claims 4-30 are only entitled to "priority to the instant filing date of July 8, 2003" (Office Action at page 2, line 21). Applicants traverse this contention.

The Office alleges that "neither [the] '900 nor '912 . . . applications provide adequate written description of the genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1 or nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43 or 59-163 of SEQ ID NO: 2." (Office Action at page 2).

MPEP §2163 explains that "[t]o . . . be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." In this regard, MPEP §2163 further explains that:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut

> the presumption . . . . The examiner has the initial burden of presenting by a *preponderance of evidence* why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims . . . . In rejecting a claim, the examiner must set forth *express findings of fact* regarding the above analysis which support the lack of written description conclusion. These findings should . . . provid[e] reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description (emphasis added).

In the section entitled "Priority," the Office does not provide any support for the assertion that the disputed genera have inadequate written description. The lack of support is not overcome even if the statements provided by the Office in its separate written description rejection of claims 4-30 are imputed to the priority assertion. The Office's stated grounds for the written description rejection is not commensurate in scope with the unsupported allegation set forth in the statement on Priority. Accordingly, the Office has not met its burden to support its position on priority with respect to claims reciting a "genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1 or nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43 or 59-163 of SEQ ID NO: 2."

Even if the Office had supported its priority assertion (which is not admitted), Applicants respectfully submit that the '912 Application provides implicit and explicit description of species in a "genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1" and "nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43 or 59-163 of SEQ ID NO: 2," which description is sufficient to support the genus. Such implicit and explicit description is found in the '912 Application, at least, as follows:

1. Nucleotides encoding the Pin1 protein, which includes the WW and PPIase domains, are prototypical examples of nucleic acid sequences encoding those domains. Pin1-encoding nucleic acid sequences are described throughout the '912 Application, including original claims 7 and 8, and representative paragraphs beginning on page 9, line 3 through page 10, line 24.

2. The '912 Application (at page 9, lines 5-6) specifically describes "polynucleotides encoding all or a portion of Pin1 . . . as long as they encode a polypeptide with Pin1 activity." Polynucleotides encoding biologically active fragments and smaller peptides also fall within the genus of nucleotides encoding the WW domain or PPIase domain.
3. The nucleic acid molecules encoding Pin1 fusion polypeptides HA-Pin1 and His-Pin1 (disclosed at least in Examples 4 and 5 of the '912 Application) are further examples of species in the "genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1" and "nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43 or 59-163 of SEQ ID NO: 2."
4. The '912 Application also inherently discloses and expressly describes fusions between the GAL4 transactivation domain and Pin1 fragments. Example 2 (beginning on page 31) discloses a GAL4 transactivation domain-HELA cell cDNA fusion library, which was used as the prey in a yeast two-hybrid system for identifying NIMA-binding proteins. Because Pin1 proteins were successfully isolated in this example, the fusion expression library must include a population of nucleic acid molecules encoding GAL4-Pin1 fusion proteins. In particular, the paragraph beginning at page 34, line 10 describes particular GAL4-Pin1 clones isolated from the yeast two-hybrid screen:

> The fusion points between GAL4 and Pin1 in six different isolated clones were: clone H2O at C-9; clone H16, 24 and 38 at G+13; clones H6 and H36 at C+15.

These clones represent fusions of the nucleic acid sequence encoding the GAL4 transactivation domain with a nucleic acid sequence encoding full-length Pin1 (clone H2O), and with a nucleic acid sequence encoding Pin1 lacking its N-terminal four or five amino acids (clone H16, 24 and 38, or clones H6 and H36). These GAL4-Pin1 fusion constructs are also representative species in the genus of polynucleotides including nucleotides 13-129 or 175-489 of SEQ ID NO:1, and the genus of polynucleotides encoding polypeptides including amino acid 5-43 or 59-163 of SEQ ID NO:2.

Moreover, the Office's allegation that the '912 Application fails to provide adequate written description for the presently claimed genus is contrary to the analysis provided in the Synopsis of Application of Written Description Guidelines

(http://www.uspto.gov/web/menu/written.pdf) ("Written Description Guidelines), in particular Example 8 (see pages 33-35 of the guidelines). The specification of the '912 Application at least teaches a nucleic acid that encodes a full-length polypeptide containing well-defined domains with specific activities, *i.e.* peptidyl prolyl isomerase activity and WW domain binding activity. A review of the specification further indicates that the nucleotide sequence of SEQ ID NO:1, the amino acid sequence of SEQ ID NO:2 and fragments that demonstrate peptidyl prolyl isomerase or WW domain binding activity are the core features of the claimed invention. Furthermore, the nucleic acid and amino acid sequences of SEQ ID NO:1 and SEQ ID NO:2 have been deemed to be novel and unobvious (see, *e.g.*, U.S. Patent Nos. 5,952,467 and 5,972,697).

The presently claimed subject matter is drawn to a genus, *i.e.,* nucleic acids that minimally encode a functional fragment of the polypeptide of SEQ ID NO:2 which has peptidyl prolyl isomerase activity or WW domain binding activity. The claims read on the claimed encoding sequences in any construct or with additional nucleic acid residues placed at either end of the encoding sequence.

One skilled in the art can readily envisage nucleic acid molecule which include nucleic acid sequences encoding portions of SEQ ID NO:2 which have the specified functional limitations, *i.e.,* peptidyl prolyl isomerase activity or WW domain binding activity. For example, one skilled in the art would understand that insertion of these sequences into known vectors is a matter of routine. Thus, although there may be substantial variability among the species of nucleic acids encompassed within the scope of the claims because the nucleic acid sequences encoding the domains of Pin1 set forth in SEQ ID NO:2 may be combined with sequences known in the art (*e.g.,* expression vectors, epitope tags, *etc.*), the *necessary attribute* is the encoding sequences of SEQ ID NO:2.

Thus, weighing all of the factors, including (i) that the sequences of the full-length polypeptide and functional domains are disclosed in the '912 Application (and in the present application) and (ii) that any substantial variability within the genus arises due to the addition of elements that are not part of the inventors' particular contribution, taken in view of the level of

knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicants were in possession of the presently claimed genus of nucleic acid molecules.

Accordingly, given that the Office's assertion regarding the priority date of the claims is unsupported by evidence or findings of fact and the '912 Application clearly complies with the Written Description Guidelines with respect to a "genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1" and "nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43 or 59-163 of SEQ ID NO: 2," Applicants respectfully submit that the claims of the present application (particularly as amended herein) are entitled to claim the benefit of the filing dates of the '912 Application (*i.e.*, November 13, 1995) and any intervening continuation or divisional application(s) recited in the priority claim.

Applicants further note that the claims have been amended to recite polynucleotides encoding polypeptides, at least in part, found by the Office to be allowable in the '631 Application. As discussed above, the Examiners indicated in the Examiner Interview that claims in the present case likely would be allowable to the extent such claims recited polynucleotides encoding polypeptides allowable in the '631 Application. Because the Office found the polypeptide claims in the '631 Application to have priority to the November 13, 1995 filing date of the '912 Application (see, page 2, section entitled "Priority" in the Office action, dated January 3, 2006, issued in the '631 Application), Applicants respectfully submit that the same is true for the polynucleotides recited in the claims now pending in this application (*i.e.*, claims 6, 7, 9-11, 20, 21, 23-25, and 31-36).

Claim Rejections under 35 U.S.C. §112, second paragraph:

Claims 4-30 have been rejected under 35 U.S.C. §112, second paragraph because the phrase "substantially the same" allegedly is unclear. Applicants traverse this rejection at least because the meaning of the disputed phrase is provided in the application (*e.g.*, at page 10, lines 3-6). Nonetheless to facilitate prosecution of the application, none of the claims as amended herein recite the allegedly unclear phrase. Therefore, Applicants request that this rejection be withdrawn.

Claims 4 and 18 have been rejected under 35 U.S.C. §112, second paragraph because the term "about" in the phrase "at least about 15 contiguous nucleotides" allegedly does not make clear the amount of "variation from 15 nucleotides." Applicants traverse this rejection.

"The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification" (MPEP §2173.05(b)). "About" is a term that has expressly been found to satisfy the §112, second paragraph standard for definiteness (see MPEP §2173.05(b)). Nevertheless, for reasons unrelated to this rejection and merely to facilitate prosecution of the application, claims 4 and 18 have been canceled. Accordingly, this rejection is moot and Applicants request that it be withdrawn.

Claim Rejections under 35 U.S.C. §112, first paragraph:

Claims 4-30 have been rejected under 35 U.S.C. §112, first paragraph allegedly as being "drawn to new matter." Applicants traverse this rejection. In particular, the Office contends (at page 4, paragraph 1) that the "specification as filed . . . does not provide support for the instant amendment claims reciting nucleic acid residues which minimally comprise 13-129 or 175-489 of SEQ ID NO: 1 or nucleotide[s] comprising [a] nucleotide sequence encoding a Pin1 polypeptide minimally comprising substantially the same . . . amino acid sequence as amino acid 5-43 and 59-163 of SEQ ID NO:2 because the term 'substantially the same' allows for a variation in sequence from amino acids 5-43 and 59-163 . . . and because the claims encompass sequences which vary considerably from SEQ ID NO: 1 or the polynucleotides which encode SEQ ID NO: 2."

As discussed above, claim 4-30 have been amended to remove the disputed phrase "substantially the same." Thus, this basis of support for this rejection has been rendered moot. Moreover, in the arguments presented above in connection with the Office's disputed priority determination, the application (which has the same specification as the '912 Application) is shown to describe a "genus of nucleotides comprising nucleotides 13-129 or 175-489 of SEQ ID NO: 1" and "nucleic acid[s] encoding a genus of polypeptides comprising . . . amino acid[s] 5-43

or 59-163 of SEQ ID NO: 2." Based on these amendments, bases for written description, and arguments alone, Applicants believe this rejection should be withdrawn.

Nevertheless, to facilitate prosecution of the application, Applicants have amended the claims to recite polynucleotides encoding polypeptides already indicated by the Office to be allowable or reasonably believed by Applicant to be allowable in the '631 Application. Because the Office implicitly has determined in the '631 Application that the genus of allowable polypeptides has been described by "a representative number of species" in satisfaction of the written description requirement, then, logically, the polynucleotides encoding such allowable polypeptides claimed in the present application must also be described by "a representative number of species" in satisfaction of the written description requirement. In view of the foregoing claim amendments and discussion, Applicants request that this rejection be withdrawn.

Claims 4-5 and 18-19 have been rejected under 35 U.S.C. §112, first paragraph (written description) because, allegedly, "[t]he specification does not 'clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" In particular, the Office alleges that "no metes or bounds can be determined for the terms 'substantially the same', 'sequence variant' or 'a portion of a Pin1 polypeptide.'" Applicants traverse this rejection. However, merely to facilitate prosecution of this application and without prejudice to pursue the canceled subject matter, claims 4-5 and 18-19 have been canceled. Thus, this rejection is moot and Applicants request that it be withdrawn.

Claim Rejections under 35 U.S.C. §102:

"The compliment (sic) of claim 4 in part" has been rejected under 35 U.S.C. §102(b) based allegedly "upon a public use or sale of the invention" as evidenced by Cat. No. 1230, Random Primer, New England Biolabs, 1993/1994 Catalog. Applicants traverse this rejection. Nevertheless, the rejection is moot by the cancellation of claim 4; accordingly, Applicants request that it be withdrawn.

Claims 4-30 have been rejected under 35 U.S.C. §102(e) allegedly as being anticipated by Baker *et al.*, U.S. Pat. App. Pub. No. 2003/0225528.

Even if Baker *et al.* taught or suggested all of the elements of the rejected claims as is required for an anticipatory reference, which is not conceded, Baker *et al.* is not available as prior art against the present application. As argued extensively above, the claims as amended herein are entitled to the benefit of the November 13, 1995 filing date of the '912 Application. Thus, for purposes of §102(e), Applicants have a November 13, 1995 constructive date of invention. At best, Baker *et al.* may have a constructive invention date of September 18, 2002 (which is the filing date of the U.S. provisional application to which Baker *et al.* claim priority). Clearly, therefore, Baker *et al.* cannot describe an "invention . . . by another . . . before the invention by the applicant for patent," as required by 35 U.S.C. §102(e). Accordingly, Applicants request that this rejection be withdrawn.

Claims 18-30 have been rejected under 35 U.S.C. §102(e) allegedly as being anticipated by Matthews *et al.*, U.S. Pat. App. Pub. No. 2004/00171019.

Even if Matthews *et al.* taught or suggested all of the elements of the rejected claims as is required for an anticipatory reference, which is not conceded, Matthews *et al.* is not available as prior art against the present application. As argued extensively above, the claims as amended herein are entitled to the benefit of the November 13, 1995 filing date of the '912 Application. Thus, for purposes of §102(e), Applicants have a November 13, 1995 constructive date of invention. At best, Matthews *et al.* may have a constructive invention date of July 9, 2002 (which is the filing date of the U.S. provisional application to which Matthews *et al.* claim priority). Clearly, therefore, Matthews *et al.* cannot describe an "invention . . . by another . . . before the invention by the applicant for patent," as required by 35 U.S.C. §102(e). Accordingly, Applicants request that this rejection be withdrawn.

New Claims 31-34

New claims 31-34 recite polynucleotides encoding polypeptides that the Office has found allowable or that Applicants reasonably believe are allowable based on the Examiner Interview

and prosecution in the '631 Application. Thus, it is believed these claims satisfy all of the requirements for patentability.

New claims 35 and 36

New claims 35 and 36 are supported by the specification, at least, at page 12, line 24 through page 14, line 6. Applicants further note that the restriction requirement (dated June 23, 1997) issued in the '912 Application alleged "DNA encoding Pin1protein, vector, and host cell" to be a single invention. Thus, claims 35 and 36 are properly included in this divisional application directed to nucleic acid molecules encoding Pin1 polypeptides and fragments thereof.

CONCLUSION

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned attorney prior to issuance of the next Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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